

FROM :

FAX NO. :

RECEIVED
CENTRAL FAX CENTER

OCT 17 2008 04:37PM P2

OCT 07 2010

Doc Code: PPH.PCT.652

Document Description: Petition to make special under PCT-Patent Pros Hwy

PTO/SB/20PCT-EP (05-10)

Approved for use through 01/31/2012. OMB 0651-0058

U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**REQUEST FOR PARTICIPATION IN THE PATENT COOPERATION TREATY - PATENT PROSECUTION
HIGHWAY (PCT-PPH) PILOT PROGRAM BETWEEN THE EUROPEAN PATENT OFFICE (EPO) AND
THE USPTO**

Application No:	10/555,895	Filing date:	US Filing Date: November 2, 2006
-----------------	------------	--------------	----------------------------------

First Named Inventor:	Jeffrey E. Yeung
-----------------------	------------------

Title of the Invention:	Treating Back Pain by Re-Establishing the Exchange of Nutrient & Waste
----------------------------	--

**THIS REQUEST FOR PARTICIPATION IN THE PCT-PPH PILOT PROGRAM ALONG WITH THE REQUIRED DOCUMENTS MUST BE
SUBMITTED VIA EFS-WEB. INFORMATION REGARDING EFS-WEB IS AVAILABLE AT
[HTTP://WWW.USPTO.GOV/EFB/EFB_HELP.HTML](http://www.uspto.gov/efsb/efs_help.html)**

**APPLICANT HEREBY REQUESTS PARTICIPATION IN THE PCT-PPH PROGRAM AND PETITIONS TO MAKE THE
ABOVE-IDENTIFIED APPLICATION SPECIAL UNDER THE PCT-PPH PROGRAM.**

The above-identified application is (1) a national stage entry of the corresponding PCT application, or (2) a national stage entry of another PCT application which claims priority to the corresponding PCT application, or (3) a national application that claims domestic/ foreign priority to the corresponding PCT application, or (4) a national application which forms the basis for the priority claim in the corresponding PCT application, or (5) a continuing application of a U.S. application that satisfies one of (1) to (4) above, or (6) a U.S. application that claims domestic benefit to a U.S. provisional application which forms the basis for the priority claim in the corresponding PCT application.

The corresponding PCT PCT/US2004/014368
application number(s) is/are:

The international date of the corresponding
PCT application(s) is/are: May 7, 2004

I. List of Required Documents:

- a. A copy of the latest international work product (WO/ISA, WO/IPEA, or IPER) in the above-identified corresponding PCT application(s)

☐ Is attached

☒ Is not attached because the document is already in the U.S. application.

- b. A copy of all claims which were indicated as having novelty, inventive step and industrial applicability in the above-identified corresponding PCT application(s).

☒ Is attached.

☐ Is not attached because the document is already in the U.S. application.

- c. English translations of the documents in a. and b. above are attached (if the documents are not in the English language). A statement that the English translation is accurate is attached for the document in b. above.

(Page 1 of 2)
This collection of information is required by 35 U.S.C. 119, 37 CFR 1.55, and 37 CFR 1.102(d). The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

FAX NO. :

Jul. 27 2008 04:38PM P3

OCT 07 2010

PTO/SB/20PCT-EP (05-10)

Approved for use through 01/31/2012. OMB 0651-0058

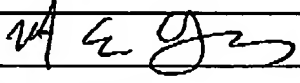
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR PARTICIPATION IN THE PCT-PPH PILOT PROGRAM BETWEEN THE EPO AND THE USPTO



(continued)

Application No.:		
First Named Inventor:		
<p>d. (1) An information disclosure statement listing the documents cited in the International work products (ISR, WO/ISA, WO/IPEA, IPER) of the corresponding PCT application.</p> <p><input checked="" type="checkbox"/> Is attached</p> <p><input type="checkbox"/> Has already been filed in the above-identified U.S. application on _____</p> <p>(2) Copies of all documents (except) for U.S. patents or U.S. patent application publications)</p> <p><input type="checkbox"/> Are attached.</p> <p><input checked="" type="checkbox"/> Have already been filed in the above-identified U.S. application on _____</p>		
II. Claims Correspondence Table:		
Claims in US Application	Patentable Claims in the corresponding PCT Application	Explanation regarding the correspondence
1-91	1-91	The US Application claims are same as PCT Application.
92-98	new	These kit claims were added & approved by EPO.
III. All the claims in the US application sufficiently correspond to the patentable claims in the corresponding PCT application.		

Signature: 	Date: October 7, 2010
Name: (Print/Typed) Jeffrey E. Yeung	Registration Number:

[Page 2 of 2]

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

Europäisches Patentamt	European Patent Office	Office européen des brevets
Urkunde Certificate Certificat		
Es wird hiermit bescheinigt, dass für die in der Patentschrift beschriebene Erfindung ein europäisches Patent für die in der Patentschrift bezeichneten Vertragsstaaten erteilt worden ist.	It is hereby certified that a European patent has been granted in respect of the invention described in the patent specification for the Contracting States designated in the specification.	Il est certifié qu'un brevet européen a été délivré pour l'invention décrite dans le fascicule de brevet pour les États contractants désignés dans le fascicule de brevet.
Europäisches Patent Nr.	European Patent No.	Brevet européen n°
1620024		
Patentinhaber	Proprietor of the Patent	Titulaire du brevet
Alleva Medical, Inc. 834 North White Road San Jose, CA 95127-1024/US		
		
		
München, den 04.08.07		Alain Pompidou Präsident des Europäischen Patentamts President of the European Patent Office Président de l'Office européen des brevets

FROM :

FAX NO. :

OCT 07 2010

Jul. 27 2008 04:40PM P5

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

(19)



(11)

EP 1 620 024 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
04.04.2007 Bulletin 2007/14

(51) Int Cl.:
A61B 17/88 (2006.01)

(21) Application number: 04760924.3

(86) International application number:
PCT/US2004/014368

(22) Date of filing: 07.05.2004

(87) International publication number:
WO 2004/101015 (25.11.2004 Gazette 2004/48)

(54) DEVICE FOR TREATING BACK PAIN BY RE-ESTABLISHING THE EXCHANGE OF NUTRIENT
AND WASTE

VORRICHTUNG ZUR BEHANDLUNG VON RÜCKENSCHMERZEN DURCH
WIEDERHERSTELLUNG DES AUSTAUSCHES VON NÄHRSTOFFEN & ABFALLSTOFFEN

DISPOSITIF POUR LE TRAITEMENT DU MAL DE DOS PAR LE RETABLISSEMENT DE L'ECHANGE
D'ELEMENTS NUTRITIFS ET DE DECHETS

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HU IE IT LI LU MC NL PL PT RO SE SI SK TR

(72) Inventor: YEUNG, Jeffrey, E.
San Jose, CA 95127-1024 (US)

(30) Priority: 07.05.2003 US 468770 P
20.06.2003 US 480057 P
16.09.2003 US 503553 P
12.12.2003 US 529065 P

(74) Representative: Stainthorpe, Vanessa Juliet et al
Harrison Goddard Foote,
Fountain Precinct
Balm Green
Sheffield S1 2JA (GB)

(43) Date of publication of application:
01.02.2005 Bulletin 2005/05

(56) References cited:
WO-A-02/17825 DE-A- 4 440 346
FR-A- 2 586 183 US-A1- 2001 053 914

(73) Proprietor: Aleeva Medical, Inc.
San Jose CA 95127-1024 (US)

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

23

EP 1 620 024 B1

24

endorphin, enkephalin, ergocalciferol, erythropoietin, follicle stimulating hormone, γ -aminobutyrate, gastrin, ghrelin, glucagon, glucocorticoids, gonadotropin-releasing hormone, growth hormone-releasing hormone, human chorionic gonadotropin, human growth hormone, insulin, insulin-like growth factor, leptin, lipotropin, luteinizing hormone, melanocyte-stimulating hormone, melatonin, mineralocorticoids, neuropeptide Y, neurotransmitter, noradrenaline, oestrogens, oxytocin, parathyroid hormone, peptide, pregnenolone, progesterone, prolactin, pro-opiomelanocortin, PYY-336, renin, secretin, somatostatin, testosterone, thrombopoietin, thyroid-stimulating hormone, thyrotropin-releasing hormone, thyroxine, triiodothyronine, trophic hormone, serotonin, vasopressin, or other therapeutic products.

[0070] The products (hormones, peptides, neurotransmitter, enzymes, catalysis or substrates) generated within the shunted disc 100 may be able to regulate bodily functions including blood pressure, energy, neuro-activity, metabolism, activation and suppression of gland activities. Some hormones and enzymes govern, influence or control eating habits and utilization of fat or carbohydrates. These hormones or enzymes may provide weight loss or gain benefits. Producing neurotransmitters, such as dopamine, adrenaline, noradrenaline, serotonin or γ -aminobutyrate, from the donor cells 277 within the shunted disc 100 can treat depression, Parkinson's disease, learning disability, memory loss, attention deficit, behavior problems, mental or neuro-related disease.

[0071] Release of the products biosynthesized by the donor cells 277 within the shunted disc 100 is synchronized with body activity. During activities of daily living, the pressure within the shunted disc 100 is mostly high to expel the products biosynthesized by the donor cells 277 into circulation to meet the demands of the body. In the supine position, the flow within the shunts 126 is reversed, bringing nutrients and oxygen into the disc 100 to nourish the cells 277. Using islets of Langerhans from the donor's pancreas as an example, production of insulin is induced in the shunted disc 100 during sleeping hours when glucose enters into the disc 100. During waking hours when disc pressure is high, insulin is expelled through the conduits 126 into circulation to draw sugars into cell membranes for energy production. At night, the insulin released from the shunted disc 100 is minimal to prevent the hypoglycemia. In essence, products biosynthesized by the donor cells 277 are released concurrent with physical activity to meet the demands of the body.

[0072] Some biosynthesized products from the donor cells 277 are appropriately deposited through the vertebral body 159, as shown in Figure 91, then into bodily circulation. Other products may be more effectively transported through the outer annulus, as in Figure 82, and diffused through the abdomen into bodily circulation. Some other products may be far more effective by entering into the muscles 193, as shown in Figure 92.

[0073] Growth factors, buffering agents, hormones, gene therapeutic agents, nutrients, minerals, analgesics,

antibiotics or other therapeutic agents can also be injected into the shunted discs 100, similar to Figures 91-92.

[0074] It is to be understood that the present invention is by no means limited to the particular constructions disclosed herein and/or shown in the drawings, but also includes any other modification, changes or equivalents within the scope of the claims. Many features have been listed with particular configurations, curvatures, options, and embodiments. Any one or more of the features described may be added to or combined with any of the other embodiments or other standard devices to create alternate combinations and embodiments. The conduit 126 can also have a gate to regulate rate and/or flow direction of nutrient, gas and waste exchange. It is also possible to connect a pump to the conduit 126 to assist the exchange between the disc 100 and the bodily fluid. A pH electrode may be exposed near the tip of the rigid needle 220 to detect the acidity within the disc 100.

[0075] It should be clear to one skilled in the art that the current embodiments, materials, constructions, methods, tissues or incision sites are not the only uses for which the invention may be used. Different materials, constructions, methods or designs for the conduit 126 can be substituted and used. Nothing in the preceding description should be taken to limit the scope of the present invention. The full scope of the invention is to be determined by the appended claims. For clarification in claims, sheath is a rigid tubular member. The elastically curved needle 101 can be called the elastic needle.

Claims

1. A deployment device for deploying a conduit into an intervertebral disc, the deployment device comprising:

a tubular sheath,
a conduit sized and configured to fit at least partially within said tubular sheath, and
a plunger to deploy said conduit.

2. The deployment device of claim 1, wherein said tubular sheath has a beveled tip.

3. The deployment device of claim 1, further comprising a needle located at least partially within said tubular sheath, preferably wherein said conduit is located at least partially within or around said needle.

4. The deployment device of claim 1, wherein said conduit is formed of a biodegradable material, preferably chosen from the group of materials consisting of polylactate, polyglycolic, poly-lactide-co-glycolide, polycaprolactone, trimethylene carbonate, silk, catgut, collagen, poly-p-dioxanone, polydioxanone, polyanhydride, trimethylene carbonate, poly-beta-hydroxybutyrate, polyhydroxyvalerate, poly-gama-

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

25

EP 1 620 024 B1

26

ethyl-glutamate, poly-DTH-iminocarbonate, poly-bisphenol-A-iminocarbonate, poly-ortho-ester, polycyanoacrylate and polyphosphazene.

5. The deployment device of claim 1, wherein said conduit is formed of a non-degradable material, preferably chosen from the group of materials consisting of polytetrafluoroethylene, polypropylene, polyethylene, polyamide, polyester, polyurethane, silicon, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate, silk, cotton, linen, fiberglass, nickel-titanium alloy and stainless steel.
6. The deployment device of claim 1, wherein at least a portion of said conduit is coated with fibrous tissue inhibitor.
7. A deployment device for deploying a conduit into an intervertebral disc, the deployment device comprising:
 - a tubular sheath,
 - a first elastic needle having a straightened position and a curved position, said straightened position being elastically straightened within said tubular sheath, and said curved position being elastically curved and located at least partially outside said tubular sheath,
 - an actuator to move said first elastic needle between said straightened position and said curved position, and
 - a conduit sized and configured to fit at least partially within said tubular sheath.
8. The deployment device of claim 7, wherein said first elastic needle has a beveled tip and, preferably, wherein a point of said beveled tip is located on a concave side of said first elastic needle, when said first elastic needle is in said curved position.
9. The deployment device of claim 7, wherein said tubular sheath has a sharp tip and preferably, wherein said sharp tip is oriented on a convex side of said first elastic needle, when said first elastic needle is in said curved position.
10. The deployment device of claim 7, wherein said tubular sheath and said first elastic needle have non-round cross sections, preferably having similar cross-sectional shapes.
11. The deployment device of claim 7, wherein said tubular sheath and said first elastic needle have oval cross sections.
12. The deployment device of claim 7, further comprising a second elastic needle, said second elastic needle located at least partially around said first elastic needle

and preferably, wherein said first and second elastic needles have similar curvatures and said curvatures are oriented in similar directions.

13. The deployment device of claim 7, further comprising an opening extending through a wall of said tubular sheath proximate a distal end thereof.
14. The deployment device of claim 7, wherein said tubular sheath has a ramp located therein, said ramp preferably being located proximate a distal end of said tubular sheath and located proximate a convex side of said first elastic needle.
15. The deployment device of claim 7, wherein said first elastic needle is formed of nickel-titanium alloy.
16. The deployment device of claim 7, wherein said first elastic needle has a non-uniform cross-section, preferably, wherein said first elastic needle has a distal end and a proximal end, said distal end being smaller than said proximal end.
17. The deployment device of claim 7, further comprising a plunger for deploying said conduit.
18. The deployment device of claim 1 or claim 7, further comprising a coating on said tubular sheath.
19. The deployment device of claim 1 further comprising a coating on said tubular sheath or of claim 7, further comprising a coating on said first elastic needle.
20. The deployment device of claim 19, wherein the coating is chosen from the group of coatings consisting of lubricant, tissue sealant, analgesic, antibiotic, radiopaque, magnetic and echogenic agents.
21. The deployment device of claim 1 or claim 7, wherein said conduit is a tube, a multifilament or a sponge formed of a biocompatible material.
22. The deployment device of claim 1 or claim 7, wherein said conduit has a plurality of protrusions extending therefrom.
23. The deployment device of claim 1 or claim 7, wherein said conduit is formed of a multi-filament portion and a mono-filament portion.
24. The deployment device of claim 7, wherein said conduit is located within or at least partially around said first elastic needle.
25. The deployment device of claim 1 or claim 7, wherein said conduit has a coating chosen from the group of coatings consisting of antibiotic, anti-occlusive coating, lubricant, growth factor, nutrient, sulfate, mineral

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

27

EP 1 620 024 B1

28

al, buffering agent, sodium carbonate, sodium bicarbonate, alkaline, collagen, hydroxyapatite, analgesic, sealant, humectant, hyaluronate, proteoglycan, chondroitin sulfate, keratan sulfate, glycosaminoglycans, heparin, starch, stiffening agent, radiopaque coating, echogenic coating, gene, cells and stem cells.

26. The deployment device of claim 1 or claim 7, wherein said conduit has a pore size of 200 microns to 10 nanometers.

27. The deployment device of claim 1 or claim 7, wherein said conduit has channels therethrough, said channels having a diameter of 200 microns to 10 nanometers.

28. The deployment device of claim 1 or claim 7, further comprising a tube located around a central portion of said conduit.

29. The deployment device of claim 28, wherein said tube is formed of a material chosen from the group of materials consisting of polytetrafluoroethylene, polypropylene, polyethylene, polyamide, polyester, polyurethane, silicon, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate and polyethylene glycol.

30. A conduit for re-establishing exchange of nutrients and waste between an intervertebral disc and bodily circulation, the conduit comprising:

an elongated member formed of a biocompatible material, said elongated member being locatable such that a first portion of said elongated member is within a patient's nucleus pulposus within the intervertebral disc.

31. The conduit of claim 30, wherein a second portion of said elongated member is locatable such that said second portion extends through an endplate and into a vertebra.

32. The conduit of claim 30, wherein said elongated member has a second portion and a central portion, wherein said elongated member is locatable such that said central portion extends through a periphery of the intervertebral disc and said second portion extends outside the intervertebral disc.

33. The conduit of claim 30, wherein a second portion of said elongated member is locatable such that said second portion extends to an outer annulus of the intervertebral disc.

34. The conduit of claim 30, wherein said conduit is a tube, a multifilament (preferably braided) or a sponge

formed of a biocompatible material.

35. The conduit of claim 30, wherein said conduit has a plurality of protrusions extending therefrom.

36. The conduit of claim 30, wherein said conduit is formed of a multi-filament portion and a mono-filament portion.

37. The conduit of claim 30, wherein said conduit is formed of a biodegradable material.

38. The conduit of claim 30, wherein said conduit is formed of a non-degradable material.

39. The conduit of claim 30, wherein said conduit is porous and has a pore size of 200 microns to 10 nanometers.

40. The conduit of claim 30, wherein said conduit has channels therethrough, said channels each having a diameter of 200 microns to 10 nanometers.

41. The conduit of claim 30, further comprising a tube located around a central portion of said conduit, the tube preferably being formed of a material chosen from the group of materials consisting of polytetrafluoroethylene, polypropylene, polyethylene, polyamide, polyester, polyurethane, silicon, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate and polyethylene glycol.

42. The conduit of claim 30, wherein at least a portion of said conduit is coated with fibrous tissue inhibitor.

43. A kit for injecting donor cells into a patient's intervertebral disc comprising:

the conduit of any of claims 30-42, and donor cells injectable into the intervertebral disc.

44. The kit of claim 43, wherein the donor cells are from a gland, from a tissue or have an origin chosen from the group of origins consisting of the pituitary gland, hypothalamus, adrenal gland, adrenal medulla, fat cells, thyroid, parathyroid, pancreas, testes, ovary, pineal gland, adrenal cortex, liver, renal cortex, kidney, thalamus, parathyroid gland, ovary, corpus luteum, placenta, small intestine, skin cells, stem cells, gene therapy, tissue engineering and cell culture.

45. The kit of claim 43, further comprising growth factor injectable into the intervertebral disc.

46. The kit of claim 43, wherein the donor cells are capable of creating a therapeutic product or a product chosen from the group of biosynthesized products

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

29

EP 1 620 024 B1

30

consisting of adrenaline, adrenocorticotrophic hormone, aldosterone, androgens, angiotensinogen (angiotensin I and II), antidiuretic hormone, atrial-natriuretic peptide, calcitonin, calciferol, cholecalciferol, calcitriol, cholecystokinin, corticotropin-releasing hormone, cortisol, dehydroepiandrosterone, dopamine, endorphin, enkephalin, ergocalciferol, erythropoietin, follicle stimulating hormone, γ -aminobutyrate, gastrin, ghrelin, glucagon, glucocorticoids, gonadotropin-releasing hormone, growth hormone-releasing hormone, human chorionic gonadotropin, human growth hormone, insulin, insulin-like growth factor, leptin, lipotropin, luteinizing hormone, melanocyte-stimulating hormone, melatonin, mineralocorticoids, neuropeptide Y, neurotransmitter, noradrenaline, oestrogens, oxytocin, parathyroid hormone, peptide, pregnenolone, progesterone, prolactin, pro-opiomelanocortin, PYY-336, renin, secretin, somatostatin, testosterone, thrombopoietin, thyroid-stimulating hormone, thyrotropin-releasing hormone, thyroxine, triiodothyronine, trophic hormone, serotonin, and vasopressin.

Patentansprüche

1. Ausbringvorrichtung zum Ausbringen einer Leitung in eine Bandscheibe, wobei die Ausbringvorrichtung aufweist:

eine röhrenförmige Hülse, eine Leitung, die so bemessen und gestaltet ist, um wenigstens teilweise in die röhrenförmige Hülse zu passen, und einen Stößel zum Ausbringen der Leitung.

2. Ausbringvorrichtung nach Anspruch 1, wobei die röhrenförmige Hülse eine abgeschrägte Spitze hat.

3. Ausbringvorrichtung nach Anspruch 1, die weiter eine Nadel aufweist, die wenigstens teilweise innerhalb der röhrenförmigen Hülse angeordnet ist, wobei die Leitung vorzugsweise wenigstens teilweise innerhalb oder um die Nadel herum angeordnet ist.

4. Ausbringvorrichtung nach Anspruch 1, wobei die Leitung aus einem biodegradierbaren Material ausgebildet ist, das vorzugsweise ausgewählt ist aus der Gruppe der Materialien bestehend aus Polylactat, Polyglycol, Polylactid-co-Glycolid, Polycaprolacton, Trimethylencarbonat, Seide, Katgut, Kollagen, Poly-p-Dioxanon, Polydioxanon, Polyanhydrid, Trimethylencarbonat, Poly-beta-Hydroxybutyrat, Polyhydroxyvalerat, Poly-gamma-Ethylglutamat, Poly-DTH-Iminocarbonat, Poly-Bisphenol-A-Iminocarbonat, Polyorthoester, Polycyanoacrylat und Polyphosphazen.

5. Ausbringvorrichtung nach Anspruch 1, wobei die Leitung aus einem nicht abbaubaren Material ausgebildet ist, das vorzugsweise ausgewählt ist aus der Gruppe der Materialien bestehend aus Polytetrafluorethylen, Polypropylen, Polyethylen, Polyamid, Polyester, Polyurethan, Silikon, Polycarbonatetherketon, Acetalharz, Polysulfon, Polycarbonat, Seide, Baumwolle, Leinen, Fiberglas, Nickelitanlegierung und Edelstahl.

6. Ausbringvorrichtung nach Anspruch 1, wobei wenigstens ein Teil der Leitung mit dem Fasergewebeinhibitor beschichtet ist.

7. Ausbringvorrichtung zum Ausbringen einer Leitung in eine Bandscheibe, wobei die Ausbringvorrichtung aufweist:

Eine röhrenförmige Hülse, eine erste elastische Nadel mit einer gerade gerichteten Stellung und einer gekrümmten Stellung, wobei die gerade Stellung elastisch innerhalb der röhrenförmigen Hülse gerade gerichtet ist, und wobei die gekrümmte Stellung elastisch gekrümmt ist und wenigstens teilweise außerhalb der röhrenförmigen Hülse liegt, einen Betätiger, um die erste elastische Nadel zwischen der gerade gerichteten Stellung und der gekrümmten Stellung zu bewegen, und eine Leitung, die so bemessen und gestaltet ist, um wenigstens teilweise in die röhrenförmige Hülse zu passen.

8. Ausbringvorrichtung nach Anspruch 7, wobei die erste elastische Nadel eine abgeschrägte Spitze hat und wobei vorzugsweise ein Punkt der abgeschrägten Spitze an einer konkaven Seite der ersten elastischen Nadel angeordnet ist, wenn sich die erste elastische Nadel in der gekrümmten Stellung befindet.

9. Ausbringvorrichtung nach Anspruch 7, wobei die röhrenförmige Hülse eine scharfe Spitze hat und wobei die scharfe Spitze vorzugsweise auf eine konvexe Seite der ersten elastischen Nadel gerichtet ist, wenn die erste elastische Nadel in der gekrümmten Stellung ist.

10. Ausbringvorrichtung nach Anspruch 7, wobei die röhrenförmige Hülse und die erste elastische Nadel nicht-runde Querschnitte haben, wobei sie vorzugsweise ähnliche Querschnittsformen haben.

11. Ausbringvorrichtung nach Anspruch 7, wobei die röhrenförmige Hülse und die erste elastische Nadel ovale Querschnitte haben.

12. Ausbringvorrichtung nach Anspruch 7, die weiter eine zweite elastische Nadel aufweist, wobei die zwei-

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others



Office de la propriété
intellectuelle
du Canada

Un organisme
d'Industrie Canada

Canadian
Intellectual Property
Office

An Agency of
Industry Canada

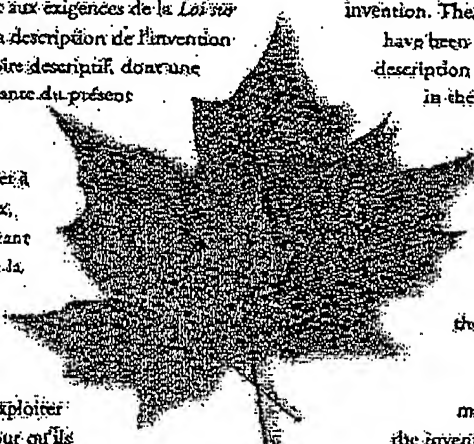
Brevet canadien / Canadian Patent

Le commissaire aux brevets a reçu une demande de délivrance de brevet visant une invention. L'adite requête satisfait aux exigences de la *Loi sur les brevets*. Le titre et la description de l'invention figurent dans le mémoire descriptif, dont une copie fait partie intégrante du présent document.

Le présent brevet confère à son titulaire et à ses représentants légaux, pour une période expirant vingt ans à compter de la date du dépôt de la demande au Canada, le droit, la faculté et le privilège exclusif de fabriquer, construire, exploiter et vendre à d'autres, pour qu'ils l'exploitent, l'objet de l'invention, sauf jugement en l'espèce rendu par un tribunal compétent, et sous réserve du paiement des taxes périodiques.

The Commissioner of Patents has received a petition for the grant of a patent for an invention. The requirements of the *Patent Act* have been complied with. The title and a description of the invention are contained in the specification, a copy of which forms an integral part of this document.

The present patent grants to its owner and to the legal representatives of its owner, for a term which expires twenty years from the filing date of the application in Canada, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication before any court of competent jurisdiction, and subject to the payment of maintenance fees.



BREVET CANADIEN

2,524,443

CANADIAN PATENT

Date à laquelle le brevet a été
accordé et délivré

2008/06/17

Date on which the patent
was granted and issued

Date du dépôt de la demande

2004/05/07

Filing date of the application

Date à laquelle la demande est
devenue accessible au public
pour consultation

2004/11/25

Date on which the application
was made available for
public inspection

Canada

Commissaire aux brevets / Commissioner of Patents

3256 (CIPRO 01) 03/07

OPIC

CIPC

OCT 07 2010

Jul. 27 2008 04:45PM P11

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others



Office de la Propriété
Intellectuelle
du Canada
Un organisme
d'Industrie Canada

Canadian
Intellectual Property
Office
An agency of
Industry Canada

CA 2524443 C 2008/06/17

(11)(21) **2 524 443**

(12) **BREVET CANADIEN
CANADIAN PATENT**

(13) **C**

(86) Date de dépôt PCT/PCT Filing Date: 2004/05/07
(87) Date publication PCT/PCT Publication Date: 2004/11/25
(45) Date de délivrance/Issue Date: 2008/06/17
(88) Entrée phase nationale/National Entry: 2005/11/02
(86) N° demande PCT/PCT Application No.: US 2004/014368
(87) N° publication PCT/PCT Publication No.: 2004/101015
(30) Priorités/Priorities: 2003/05/07 (US60/468,770);
2003/05/20 (US60/480,057); 2003/09/16 (US60/503,553);
2003/12/12 (US60/529,065)

(51) Cl.Int./Int.Cl. **A61B 17/88** (2006.01)
(72) Inventeurs/Inventors:
YEUNG, JEFFREY E., US;
YEUNG, TERESA T., US
(73) Propriétaire/Owner:
ALEEVA MEDICAL, INC., US
(74) Agent: MCFADDEN, FINCHAM

(54) Titre : TRAITEMENT DU MAL DE DOS PAR LE RETABLISSEMENT DE L'ECHANGE D'ELEMENTS NUTRITIFS & DE DECHETS
(54) Title: DEVICE FOR TREATING BACK PAIN BY RE-ESTABLISHING THE EXCHANGE OF NUTRIENT & WASTE

(57) Abrégé/Abstract:

The intervertebral disc is avascular. With aging, endplates become occluded by calcified layers, and diffusion of nutrients and oxygen into the disc diminishes. The disc degenerates, and pain ensues. Conduits are delivered and deployed into the intervertebral disc to reestablish the exchange of nutrients and waste between the disc and body circulation to stop or reverse disc degeneration and relieve pain. The intervertebral disc installed with semi-permeable conduits may be used as an immuno-isolated capsule to encapsulate donor cells capable of biosynthesizing therapeutic molecules. The semi-permeable conduits establish the exchange of nutrients and therapeutic molecules between disc and body circulation to treat a disease without using immunosuppressive drugs.

Canada

<http://opic.gc.ca> - Ottawa-Hull K1A 0C9 - <http://cipo.gc.ca>

OPIC - CIPD 191

OPIC



CIPO

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

CA 02524443 2007-10-02

What is claimed is:

1. A deployment device for deploying a porous conduit into an intervertebral disc, the deployment device comprising:
 - a sheath,
 - a porous conduit sized and configured to fit at least partially within said sheath, and
 - a plunger to deploy said porous conduit.
2. The deployment device of claim 1, wherein said sheath has a beveled tip.
3. The deployment device of claim 1 or 2, further comprising a needle located at least partially within said sheath.
4. The deployment device of claim 3, wherein said porous conduit is located at least partially within said needle.
5. The deployment device of claim 3, wherein said porous conduit is located at least partially around said needle.
6. The deployment device of any one of claims 1 to 5, further comprising a coating on said sheath.
7. The deployment device of claim 6, wherein the coating is chosen from the group of coatings consisting of lubricant, tissue sealant, analgesic, antibiotic, radiopaque, magnetic and echogenic agents.
8. The deployment device of any one of claims 1 to 7, wherein said porous conduit is a tube formed of a biocompatible material.
9. The deployment device of any one of claims 1 to 7, wherein said porous conduit is a multi-filament formed of a biocompatible material.
10. The deployment device of any one of claims 1 to 7, wherein said porous conduit is a sponge formed of a biocompatible material.

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

CA 02524443 2007-10-02

11. The deployment device of any one of claims 1 to 7, wherein said porous conduit has a plurality of protrusions extending therefrom.

12. The deployment device of claim 11, wherein said protrusions are chosen from the group consisting of flanges, knots and rings.

13. The deployment device of any one of claims 1 to 7, wherein said porous conduit is formed of a multi-filament portion and a mono-filament portion.

14. The deployment device of any one of claims 1 to 7, wherein said porous conduit is formed of a biodegradable material.

15. The deployment device of any one of claims 1 to 7, wherein said porous conduit is formed of a non-degradable material.

16. The deployment device of any one of claims 1 to 7, wherein said porous conduit is formed of a non-degradable material chosen from the group of materials consisting of polytetrafluoroethylene, polypropylene, polyethylene, polyamide, polyester, polyurethane, silicon, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate, silk, cotton, linen, fiberglass, nickel-titanium alloy and stainless steel.

17. The deployment device of any one of claims 1 to 7, wherein said porous conduit is formed of a degradable material chosen from the group of materials consisting of polylactate, polyglycolic, poly-lactide-co-glycolide, polycaprolactone, trimethylene carbonate, silk, catgut, collagen, poly-p-dioxanone, polydioxanone, polyanhydride, trimethylene carbonate, poly-beta-hydroxybutyrate, polyhydroxyvalerate, poly-gama-ethyl-glutamate, poly-DTH-iminocarbonate, poly-bisphenol-A-iminocarbonate, poly-ortho-ester, polycyanoacrylate and polyphosphazene.

18. The deployment device of any one of claims 1 to 17, wherein said porous conduit has a coating chosen from the group of coatings consisting of antibiotic, anti-occlusive coating, lubricant, growth factor, nutrient, sulfate, mineral, buffering agent, sodium carbonate,

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

CA 02524443 2007-10-02

sodium bicarbonate, alkaline, collagen, hydroxyapatite, analgesic, sealant, humectant, hyaluronate, proteoglycan, chondroitin sulfate, keratan sulfate, glycosamino-glycans, heparin, starch, stiffening agent, radiopaque coating, echogenic coating, gene, cells and stem cells.

19. The deployment device of any one of claims 1 to 18, wherein said porous conduit has a pore size of 200 microns to 10 nanometers.

20. The deployment device of any one of claims 1 to 18, wherein said porous conduit has channels therethrough, said channels having a diameter of 200 microns to 10 nanometers.

21. The deployment device of any one of claims 1 to 20, further comprising a tube located around a central portion of said porous conduit.

22. The deployment device of claim 21, wherein said tube is formed of a material chosen from the group of materials consisting of polytetrafluoroethylene, polypropylene, polyethylene, polyamide, polyester, polyurethane, silicon, poly-ether-ether-ketone, acetal resin, polysulfone, polycarbonate and polyethylene glycol.

23. The deployment device of any one of claims 1 to 17, wherein at least a portion of said porous conduit is coated with fibrous tissue inhibitor.

24. A deployment device for deploying a porous conduit into an intervertebral disc, the deployment device comprising:

a tubular sheath,

a first elastic needle having a straightened position and a curved position, said straightened position being elastically straightened within said tubular sheath, and said curved position being elastically curved and located at least partially outside said tubular sheath,

an actuator to move said first elastic needle between said straightened position and said curved position, and

a porous conduit sized and configured to fit at least partially within said tubular sheath.

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

CA 02524443 2007-10-02

25. The deployment device of claim 24, wherein said first elastic needle has a beveled tip.
26. The deployment device of claim 25, wherein a point of said beveled tip is located on a concave side of said first elastic needle, when said first elastic needle is in said curved position.
27. The deployment device of any one of claims 24 to 26, wherein said tubular sheath has a sharp tip.
28. The deployment device of claim 27, wherein said sharp tip is oriented on a convex side of said first elastic needle, when said first elastic needle is in said curved position.
29. The deployment device of any one of claims 24 to 28, wherein said tubular sheath and said first elastic needle have non-round cross sections.
30. The deployment device of claim 29, wherein said tubular sheath and said first elastic needle have similar cross-sectional shapes.
31. The deployment device of any one of claims 24 to 28, wherein said tubular sheath and said first elastic needle have oval cross sections.
32. The deployment device of any one of claims 24 to 31, further comprising a second elastic needle, said second elastic needle located at least partially around said first elastic needle.
33. The deployment device of claim 32, wherein said first and second elastic needles have similar curvatures and said curvatures are oriented in similar directions.
34. The deployment device of any one of claims 24 to 33, further comprising an opening extending through a wall of said tubular sheath proximate a distal end thereof.
35. The deployment device of any one of claims 24 to 33, wherein said tubular sheath has

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

CA 02524443 2007-10-02

a ramp located therein.

36. The deployment device of claim 35, wherein said ramp is located proximate a distal end of said tubular sheath and located proximate a convex side of said first elastic needle.

37. The deployment device of any one of claims 24 to 36, wherein said first elastic needle is formed of nickel-titanium alloy.

38. The deployment device of any one of claims 24 to 37, wherein said first elastic needle has a non-uniform cross-section.

39. The deployment device of claim 38, wherein said first elastic needle has a distal end and a proximal end, said distal end being smaller than said proximal end.

40. The deployment device of any one of claims 24 to 39, further comprising a plunger for deploying said porous conduit.

41. The deployment device of claim 24, further comprising a coating on said tubular sheath.

42. The deployment device of claim 41, wherein the coating is chosen from the group of coatings consisting of lubricant, tissue sealant, analgesic, antibiotic, radiopaque, magnetic and echogenic agents.

43. The deployment device of any one of claims 24 to 42, further comprising a coating on said first elastic needle.

44. The deployment device of claim 43, wherein the coating is chosen from the group of coatings consisting of lubricant, tissue sealant, analgesic, antibiotic, radiopaque, magnetic and echogenic agents.

45. The deployment device of any one of claims 24 to 44, wherein said porous conduit is a tube formed of a biocompatible material.

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

CA 02524443 2007-10-02

46. The deployment device of any one of claims 24 to 44, wherein said porous conduit is a multi-filament formed of a biocompatible material.

47. The deployment device of any one of claims 24 to 44, wherein said porous conduit is a sponge formed of a biocompatible material.

48. The deployment device of any one of claims 24 to 44, wherein said porous conduit has a plurality of protrusions extending therefrom.

49. The deployment device of any one of claims 24 to 44, wherein said porous conduit is formed of a multi-filament portion and a mono-filament portion.

50. The deployment device of any one of claims 24 to 49, wherein said porous conduit is located within said first elastic needle.

51. The deployment device of any one of claims 24 to 49, wherein said porous conduit is located at least partially around said first elastic needle.

52. The deployment device of any one of claims 24 to 51, wherein said porous conduit has a coating chosen from the group of coatings consisting of antibiotic, anti-occlusive coating, lubricant, growth factor, nutrient, sulfate, mineral, buffering agent, sodium carbonate, sodium bicarbonate, alkaline, collagen, hydroxyapatite, analgesic, sealant, humectant, hyaluronate, proteoglycan, chondroitin sulfate, keratan sulfate, glycosaminoglycans, heparin, starch, stiffening agent, radiopaque coating, echogenic coating, gene, cells and stem cells.

53. The deployment device of any one of claims 24 to 52, wherein said porous conduit has a pore size of 200 microns to 10 nanometers.

54. The deployment device of any one of claims 24 to 52, wherein said porous conduit has channels therethrough, said channels having a diameter of 200 microns to 10 nanometers.

US 10/555895, PCT/US2004/14368, EU Patent 1620024, Canadian Patent 2524443 & Others

CA 02524443 2007-10-02

55. The deployment device of any one of claims 24 to 54, further comprising a tube located around a central portion of said porous conduit.

56. A porous conduit for re-establishing exchange of nutrients and waste between an intervertebral disc and bodily circulation, the porous conduit comprising:
an elongated member formed of a biocompatible material, said elongated member having a first portion adapted for insertion within a patient's nucleus pulposus within the intervertebral disc.

57. The porous conduit of claim 56, wherein said elongated member has a second portion adapted to extend through an endplate and into a vertebra.

58. The porous conduit of claim 56, wherein said elongated member has a second portion and a central portion, wherein said central portion is adapted to extend through a periphery of the intervertebral disc and said second portion is adapted to extend outside the intervertebral disc.

59. The porous conduit of claim 56, wherein said elongated member has a second portion which is adapted to extend to an outer annulus of the intervertebral disc.

60. The porous conduit of any one of claims 56 to 59, wherein said porous conduit is a tube formed of a biocompatible material.

61. The porous conduit of any one of claims 56 to 59, wherein said porous conduit is a multi-filament formed of a biocompatible material.

62. The porous conduit of claim 61, wherein said multi-filament is braided.

63. The porous conduit of any one of claims 56 to 59, wherein said porous conduit is a sponge formed of a biocompatible material.